

## REMARKS

### I. Introduction

Applicants respectfully request reconsideration of the present application in view of the following remarks.

Applicants appreciate the courtesies extended to Mr. Mantelle and the undersigned by Examiner Ghali during the personal interview on March 29, 2004.

### II. Status of the Claims

Claims 16, 17, 33 and 34 were cancelled previously. Thus, claims 1-15, 18-32 and 35 are pending. Despite Applicants' previous arguments, the Examiner has maintained the restriction requirement, thereby withdrawing from examination claims 18-32 and 35. Consequently, claims 1-15 are now subject to examination on the merits.

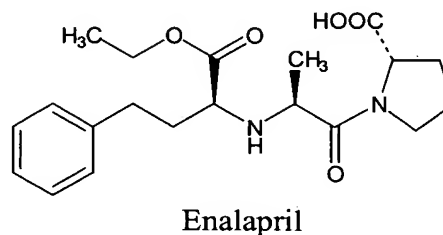
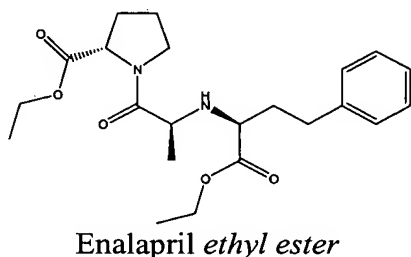
### III. The Office Action

#### A. Rejection of Claims Under 35 U.S.C. § 102(e)

Claim 9 stands rejected as being allegedly anticipated by U.S. Pat. No. 6,387,894 to Fossa ("Fossa"). Office Action at page 4. In the Examiner's opinion, Fossa discloses a composition comprising the ethyl ester of enalapril together with a pharmaceutically acceptable carrier. The Examiner also believes Fossa to disclose the administration of the composition via a transdermal route. Applicants respectfully traverse the rejection.

It is well settled that an invention lacks novelty under 35 U.S.C. § 102 *only* if each and every element of the claim is described or disclosed, either explicitly or inherently, in a single prior art reference. *See Finnigan Corp. v. International Trade Com'n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999). In fact, the identical invention must be shown in as complete detail as is contained in the claim. *See Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Here, Fossa plainly does not disclose the ethyl ester of enalapril. Drawing the Examiner's attention to the cited passage, *see* Fossa at col. 12, ll. 11-13, Applicants respectfully point out that Fossa discloses only enalapril, whose chemical name is 1-[N-[(S)-

1-carboxy-3-phenylpropyl]-L-alanyl]-L-proline-1'-ethyl ester. The structural distinction between enalapril ethyl ester, *see* specification at paragraph 9, and enalapril is thus illustrated as shown below:



Thus, Fossa does not teach enalapril ethyl ester nor any composition comprising the same. Additionally, there is no suggestion whatsoever in the reference of enalapril ethyl ester or a composition thereof. Because Fossa does not disclose each element of claim 9, Fossa does not anticipate the claim. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection.

#### **B. Rejection Under 35 U.S.C. § 103**

Claims 1-15 stand rejected as being allegedly obvious over Fossa in view of U.S. Pat. Appln. Pub. No. 2002/004065 to Kanios ("Kanios"). In the Examiner's opinion, Fossa does not teach the claimed flux rate, pressure sensitive adhesives, and permeation enhancers. Thus, the Examiner relies upon Kanios for its purported disclosure of a method of transdermally delivering a drug that provides a release rate regulating effect on the active agent. According to the Examiner, the active agent can be *enalapril*. Additionally, the Examiner further relies upon Kanios for its alleged disclosure of certain pressure sensitive adhesives and permeation enhancers. The Examiner thus concludes that a person of ordinary skill would have been motivated to administer the enalapril ethyl ester allegedly disclosed by Fossa in the method as taught by Kanios because the method of Kanios implicates a zero-order release rate of the active agent. Applicants respectfully traverse this rejection.

# **1. Kanios is Not Prior Art**

As an initial matter, Applicants submit that Kanios is excluded as prior art under 35 U.S.C. § 103(c). That section provides that:

[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

In the present case, the Examiner has not specified the paragraph of section 102 under which Kanios would allegedly qualify as prior art, but it is clear that there are no allegations of Kanios being a statutory bar. Applicants presume the Examiner to apply Kanios under one of sections 102(e), (f), or (g).<sup>1</sup> There is no allegation of Applicants not being the true inventors, 35 U.S.C. § 102(f), nor is the present application the subject of an interference proceeding, *id.* at 102(g). Consequently, Applicants understand the Examiner to apply Kanios under section 102(e).

Kanios and the subject matter of the presently claimed invention were both subject to an obligation of assignment to the same person, namely Noven Pharmaceuticals, Inc., at the time of the present invention, as evidenced by the present inventors' later assignment, executed on January 22, 2002, to Noven Pharmaceuticals, Inc.. Additionally, the subject matter of Kanios was developed by "another" with respect to the present inventive entity.

Having thus satisfied each of the requirements under 35 U.S.C. § 103(c), Applicants respectfully submit that Kanios is not available as prior art. Consequently, the present rejection now turns upon the sole reference of Fossa.

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<sup>1</sup> Since Kanios is a U.S. patent application, it would not qualify as prior art under section 102(a).

## 2. Fossa Does not Teach or Suggest the Claimed Invention

Turning to Fossa, for the reasons set forth above, Applicants respectfully submit that Fossa does not teach or suggest the claimed invention since Fossa does not disclose or suggest enalapril ethyl ester. Moreover, as recognized by the Examiner, Fossa does not disclose or suggest the claimed flux rate, pressure sensitive adhesives, and permeation enhancers, and therefore does not obviate the present invention. Accordingly, Applicants courteously request the Examiner to reconsider and withdraw the present rejection.

## IV. Conclusion

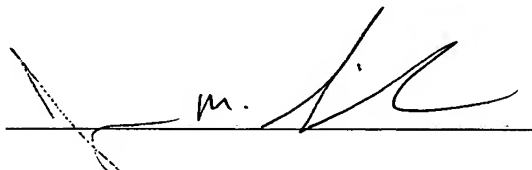
On the belief that all of the outstanding rejections have been overcome, Applicants respectfully submit that the present application is in condition for allowance. Therefore, Applicants request favorable reconsideration of the application in light of the foregoing commentary. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.